

AMENDED IN SENATE MAY 2, 2000
AMENDED IN SENATE APRIL 24, 2000
AMENDED IN SENATE APRIL 13, 2000

SENATE BILL

No. 2046

Introduced by Senator Speier

February 25, 2000

An act to amend Section 1367.21 of the Health and Safety Code, and to amend Section 10123.195 of the Insurance Code, relating to health care.

LEGISLATIVE COUNSEL'S DIGEST

SB 2046, as amended, Speier. Health care: prescription drug coverage.

Existing law provides for the regulation and licensing of health care service plans by the Department of Managed Care, effective no later than July 1, 2000, or earlier pursuant to an Executive order of the Governor. A willful violation of the provisions governing health care service plans is a crime. Existing law provides for the regulation of policies of disability insurance by the Insurance Commissioner.

Existing law prohibits a health care service plan contract, and specified disability insurance policies, from limiting or excluding coverage for a drug on the basis that the drug is prescribed for a use different than the use for which the drug has been approved for marketing by the federal Food and Drug Administration if specified conditions are met, including that the drug prescribed is for the treatment of a life-threatening condition.

This bill would modify that specific condition by also including a drug that is prescribed for a chronic and disabling condition. This bill would define “chronic and disabling.”

Because a violation of this bill’s requirements with respect to coverage under a health care service plan contract would be a crime, this bill would impose a state-mandated local program by creating a new crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1367.21 of the Health and Safety
2 Code is amended to read:

3 1367.21. (a) No health care service plan contract
4 which covers prescription drug benefits shall be issued,
5 amended, delivered, or renewed in this state if the plan
6 limits or excludes coverage for a drug on the basis that the
7 drug is prescribed for a use that is different from the use
8 for which that drug has been approved for marketing by
9 the federal Food and Drug Administration (FDA),
10 provided that all of the following conditions have been
11 met:

12 (1) The drug is approved by the FDA.

13 (2) The drug is prescribed by a participating licensed
14 health care professional for the treatment of a chronic
15 and disabling or life-threatening condition.

16 (3) The drug has been recognized for treatment of
17 that condition by one of the following:

18 (A) The American Medical Association Drug
19 Evaluations.

20 (B) The American Hospital Formulary Service Drug
21 Information.



(C) The United States Pharmacopoeia Dispensing Information, Volume 1, “Drug Information for the Health Care Professional.”

(D) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

(d) For purposes of this section “life-threatening” means either or both of the following:

(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.

(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

(e) For purposes of this section “chronic and disabling” means either or both of the following:

(1) Diseases or conditions where the likelihood of interference with one or more of the *significant* activities of daily living is high if left untreated.

(2) Diseases or conditions that are likely to persist over a period of years, where the end point of clinical intervention is preventing the loss of ability to engage in one or more of the *significant* activities of daily living.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the plan.

(g) Nothing in this section shall be construed to prevent the application of reasonable deductible or copayment provisions.

1 (h) Health care service plan contracts for the delivery
2 of Medi-Cal services under the Waxman-Duffy Prepaid
3 Health Plan Act (Chapter 8 (commencing with Section
4 14200) of Part 3 of Division 9 of the Welfare and
5 Institutions Code) are exempt from the requirements of
6 this section.

7 SEC. 2. Section 10123.195 of the Insurance Code is
8 amended to read:

9 10123.195. (a) No group or individual disability
10 insurance policy issued, delivered, or renewed in this
11 state or certificate of group disability insurance issued,
12 delivered, or renewed in this state pursuant to a master
13 group policy issued, delivered, or renewed in another
14 state that, as a provision of hospital, medical, or surgical
15 services, directly or indirectly covers prescription drugs
16 shall limit or exclude coverage for a drug on the basis that
17 the drug is prescribed for a use that is different from the
18 use for which that drug has been approved for marketing
19 by the federal Food and Drug Administration (FDA),
20 provided that all of the following conditions have been
21 met:

22 (1) The drug is approved by the FDA.

23 (2) The drug is prescribed for the treatment of a
24 chronic and disabling or life-threatening condition.

25 (3) The drug has been recognized for treatment of
26 that condition by one of the following:

27 (A) The American Medical Association Drug
28 Evaluations.

29 (B) The American Hospital Formulary Service Drug
30 Information.

31 (C) The United States Pharmacopoeia Dispensing
32 Information, Volume 1, "Drug Information for the Health
33 Care Professional."

34 (D) Two articles from major peer reviewed medical
35 journals that present data supporting the proposed
36 off-label use or uses as generally safe and effective unless
37 there is clear and convincing contradictory evidence
38 presented in a major peer reviewed medical journal.

39 (b) It shall be the responsibility of the prescriber to
40 submit to the insurer documentation supporting

1 compliance with the requirements of subdivision (a), if
2 requested by the insurer.

3 (c) Any coverage required by this section shall also
4 include medically necessary services associated with the
5 administration of a drug subject to the conditions of the
6 contract.

7 (d) For purposes of this section “life-threatening”
8 means either or both of the following:

9 (1) Diseases or conditions where the likelihood of
10 death is high unless the course of the disease is
11 interrupted.

12 (2) Diseases or conditions with potentially fatal
13 outcomes, where the end point of clinical intervention is
14 survival.

15 (e) For purposes of this section “chronic and
16 disabling” means either or both of the following:

17 (1) Diseases or conditions where the likelihood of
18 interference with one or more of the *significant* activities
19 of daily living is high if left untreated.

20 (2) Diseases or conditions that are likely to persist over
21 a period of years, where the end point of clinical
22 intervention is preventing the loss of ability to engage in
23 one or more of the *significant* activities of daily living.

24 (f) The provision of drugs and services when required
25 by this section shall not, in itself, give rise to liability on
26 the part of the insurer.

27 (g) This section shall not apply to a policy of disability
28 insurance that covers hospital, medical, or surgical
29 expenses which is issued outside of California to an
30 employer whose principal place of business is located
31 outside of California.

32 (h) Nothing in this section shall be construed to
33 prevent the application of reasonable deductible or
34 copayment provisions.

35 SEC. 3. No reimbursement is required by this act
36 pursuant to Section 6 of Article XIII B of the California
37 Constitution because the only costs that may be incurred
38 by a local agency or school district will be incurred
39 because this act creates a new crime or infraction,
40 eliminates a crime or infraction, or changes the penalty

1 for a crime or infraction, within the meaning of Section
2 17556 of the Government Code, or changes the definition
3 of a crime within the meaning of Section 6 of Article
4 XIII B of the California Constitution.

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